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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,491	Applicant(s) TANG ET AL.	
	Examiner Terry A. McKelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-45 is/are pending in the application.
 4a) Of the above claim(s) 21-23,30,31 and 34-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/27/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Attachment</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 24-29 and 32-33 in the reply filed on 8/27/03 is acknowledged. The traversal is on the ground(s) that unity of invention exists among all of the claims. This is not found persuasive because of the following reasons.

Concerning Example 17, Part 2 of Annex B concerning unity of invention between claims to polypeptide sequences and polynucleotide sequences encoding those polypeptides. This example is simply a non-binding example. The simple fact of the matter is that the exact claims set forth in the instant application to polypeptides and polynucleotides do lack a special technical feature in common because polypeptides are polymers of amino acids that have a chemical structure that is in no way chemically related to polynucleotides which are polymers of nucleotides and phosphate. How can two chemical compounds which are unrelated in structure have the same special technical feature when there is nothing else to the claimed compounds except their structures? The fact that one compound can be used as a template to produce the other compound does not show a special technical feature in common because it is drawn

Art Unit: 1636

to a relationship which is quite different from what is being claimed, simply the isolated compounds themselves.

The applicant also argues that unity of invention exists among all of Applicant's claims, that the claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicant's claims, which serve to technically interrelate all of Applicant's claims and define a contribution over the art, and antibody claim 31 is technically interrelated to the polypeptide claims since that claim recites an antibody which specifically binds the polypeptide. These arguments are not persuasive because for the antibody, it does not have the same special technical feature because it is drawn to a chemical compound which has no chemical structure in common with the polypeptide and thus it does not share a special technical feature in common. Concerning the remaining claims, they are all drawn to methods of making or methods of using the polypeptides or polynucleotides. These methods do not have a special technical feature in common because the polypeptides and polynucleotides special technical feature is drawn to the chemical structures of these compounds, and special technical features of methods are drawn to method steps, not chemical structures. In PCT lack of unity rules, methods are in separate

Art Unit: 1636

groups from products for this reason, with the clear exception that if the first claim is a product claim, then the first method of making and the first method of using the product are kept in the same group, only for the group containing the first claim that is a product. If special technical feature between products and methods of making and using the products was applicable, then all methods of making and all methods of using the product would always be kept with the product, for each product, which is clearly not the case.

The applicant also argues that there would be no burden in searching and examining Groups I, II, and IV together, and that there would be no undue burden in examining Group III with Group II and should be examined together in light of *In re Ochiai* providing rejoinder upon allowance of product claims. These arguments are not persuasive because of the following reasons. First, as the applicant noted and as noted by the restriction set forth in the last communication, PCT lack of unity rules is to be used in this 371 application. Accordingly, in establishing proper restriction, burden is not something that has to be explicitly argued in restricting between groups. lack of the same special technical feature in common between the groups is the proper restriction standard. Second, because each group does not have a common special technical feature, to

Art Unit: 1636

examine additional groups would require a search for additional different special technical features which did not have to be searched for for the other groups. This shows that there is a burden in examining the additional groups. Concerning rejoinder practice as per In re Ochiai, it does not appear to be applicable to 371 applications (and we have been given Group Director guidance to this position). The examiner will seek a positive reaffirmation that In re Ochiai rejoinder provisions are not applicable just prior to any allowance of the elected polynucleotides.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-23, 30-31, and 34-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/27/03.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

Art Unit: 1636

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the instant case, although the claim for priority is in the oath/declaration, it must also be in the first sentence of the specification.

Claim Objections

Claims 24-29 and 32-33 are objected to because of the following informalities: they all ultimately depend on non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 1636

Claims 24-29 and 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well established utility because the polynucleotides are drawn to encoding a polypeptide or particular types of fragments thereof, which polypeptide is new to the art and the specification does not show any particular activity for that polypeptide. Thus, the polynucleotides encoding the polypeptides do not have a well-established utility.

The specification asserts that the polynucleotides and the polypeptides encoded by the polynucleotides have a utility for the diagnosis, treatment, or prevention of cell proliferative, immune/inflammatory, and reproductive disorders. The utility for the claimed polynucleotides resides with the utility of the polypeptides encoded by the polynucleotides or the ability of the polynucleotide to assay for expression of the polypeptide as a diagnostic for the polypeptide. The asserted utility is not specific because a very large number of very different disorders (for treatment, diagnosis, etc) are asserted for RNAAPs in general, but none of them are specifically associated with the

Art Unit: 1636

RNAAP-1 which is encoded by the claimed polynucleotide. Also, no specific activity of the polypeptide was taught by the specification. Therefore, the asserted utility is not specific for the claimed invention.

The asserted utility is not substantial because there is no disclosed or real world utility associated with the polypeptide because the polypeptide or polynucleotide was not specifically associated with any particular disorder in the specification, and no specific activity or function for the polypeptide was taught by the specification. Thus it would require further experimentation in order to determine the specific activity of the polypeptide to support a utility or to attribute a utility to the polypeptide or polynucleotide from among the numerous treatment, diagnosis, etc, of disorders generically indicated as being potential utilities for the 17 different RNAAPs in the specification.

The specification also asserts that the polypeptide is 76% similar to human TLS-associated protein, TASR, but fails to assert a specific and substantial utility based upon this assertion of similarity.

Claims 24-29 and 32-33 are also rejected under 35 USC 112, first paragraph. Specifically, since the claimed invention is

Art Unit: 1636

not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26, 28-29, and 32-33 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides encoding a polypeptide which comprises a naturally occurring amino acid sequence at least 90% identical to SEQ ID NO:1 and a biologically active fragment of SEQ ID NO:1 (among other

Art Unit: 1636

polypeptides). The claims are also drawn to a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to SEQ ID NO:18. These claims are genus claims because they read on a large range of polypeptides and polynucleotides encoding them, limited by being naturally occurring or having a biological activity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a limitation based partly on structure (a90% identical to a particular sequence), but there is a further limitation to being naturally occurring or being a biologically active fragment, neither of which is described for the genus because only one polypeptide and one polynucleotide sequence is described by the application and no biological activity is described. Based upon the disclosure of the only polypeptide sequence and only polynucleotide sequence, the structure of other naturally occurring amino acid sequences are

Art Unit: 1636

not described or predictable, neither is the biological activity of the full length protein and thus fragments of the polypeptide that have biological activity are equally not described.

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompasses the second type of inhibitor.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides and polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it.

Art Unit: 1636

The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polynucleotide encoding SEQ ID NO:1 or comprising the specific polynucleotide sequence of SEQ ID NO:18, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1636

Claims 24 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al.

Andersson et al teach an isolated polynucleotide that comprises much more than 60 contiguous nucleotides of SEQ ID NO:18, and thus encodes a polypeptide that (in the rest of the polypeptide encoded by the polynucleotide) is a biologically active fragment of SEQ ID NO:1 and is an immunogenic fragment of SEQ ID NO:1 ("encoding" is open language). See the attached sequence comparison that shows that this reference discloses the sequence.

Claims 24 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al.

Yu et al teach an isolated polynucleotide that comprises much more than 60 contiguous nucleotides of SEQ ID NO:18, and thus encodes a polypeptide that (in the rest of the polypeptide encoded by the polynucleotide) is a biologically active fragment of SEQ ID NO:1 and is an immunogenic fragment of SEQ ID NO:1 ("encoding" is open language). See the attached sequence comparison that shows that this reference discloses the sequence.

Art Unit: 1636

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Art Unit: 1636

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

September 20, 2004

